

JUDGE ENGELMAYER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

12 CIV 5846

X ECF Case

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

Case No.

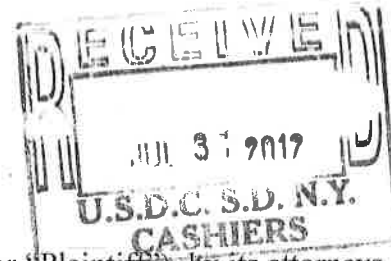
vs.

COMPLAINT

MATRIX LABORATORIES LIMITED,
N/K/A MYLAN LABORATORIES
LIMITED,

Defendant.

X



Plaintiff, Bristol-Myers Squibb Company ("BMS" or "Plaintiff"), by its attorneys, Mayer Brown LLP, as and for its Complaint against Matrix Laboratories Limited, n/k/a Mylan Laboratories Limited ("Mylan" or "Defendant"), alleges as follows:

NATURE OF THE CASE

1. This is a breach of contract case arising from Mylan's breach of an agreement (defined below) between the parties providing for the limited distribution and sale by Mylan of the well-known HIV/AIDS drug atazanavir, sold by BMS under the brand name Reyataz[®].¹
2. Pursuant to the parties' agreement dated April 17, 2011 (the "Agreement"), BMS, which owns and holds patents for Reyataz[®] in the US and many other jurisdictions, granted Mylan the right to manufacture, distribute and sell generic atazanavir in certain underdeveloped countries. The purpose of the Agreement, known as an "immunity from suit" agreement, was to enable more broad distribution of atazanavir to underdeveloped areas where there is a particularly dire need for HIV/AIDS treatment and prevention.

¹ Atazanavir sulfate is a protease inhibitor that is used in combination with other medications to treat HIV infection by blocking the enzyme that is needed for the HIV virus to multiply. The basic patent for atazanavir was filed in April 1997 by Novartis AG. BMS manufactures atazanavir under license from Novartis. BMS also holds patents on atazanavir sulfate. BMS holds patents or patent applications related to atazanavir in over 50 countries.

3. Under the Agreement, BMS – at no cost – granted Mylan the right to manufacture and sell generic atazanavir in the “Territories” listed in the Agreement – solely countries in sub-Saharan Africa and in India. This is a purely charitable endeavor by BMS as BMS agreed to forgo any royalties or profit associated with Mylan’s sale of the product pursuant to the Agreement.

4. Further, BMS provided, free of charge, the manufacturing technology necessary for Mylan to produce the compound on its own. In doing so, BMS devoted in excess of \$300,000 to ensure that Mylan could produce atazanavir.

5. In or about November, 2011, however, Mylan requested BMS’s consent to sell generic atazanavir outside the prescribed Territories and specifically into Venezuela. BMS did not consent to the sale. BMS had for at least five years supplied Reyataz[®] to Venezuela, and BMS anticipated that it would soon begin negotiations with the government of Venezuela to provide Reyataz[®] in 2012. At the time of Mylan’s request, BMS had two patent applications pending in Venezuela, *i.e.*, application numbers VN05/000854 (corresponding to BMS Docket No. 10288-VE-NP) and 1999-000084 (corresponding to BMS Docket No. GY0054A-VE-NP). BMS therefore declined its consent to Mylan’s proposed sale into Venezuela.

6. Nonetheless, in or about February, 2012, on information and belief, Mylan sold a significant amount of atazanavir to the Pan American Health Organization (“PAHO”) and shipped said atazanavir to the Venezuelan Ministry of Health, an amount believed to be equal to or in excess of a one year’s supply of the drug. Mylan knew that the purpose of this sale was to allow PAHO to distribute atazanavir in Venezuela. Upon information and belief, atazanavir is currently being sold in Venezuela.

7. This sale and shipment plainly breached the Agreement, which expressly prohibits Mylan from selling or distributing atazanavir, either directly or indirectly, into countries where BMS maintains a patent or, as here, where it has a patent pending.

8. At a minimum, Mylan's improper sale in breach of the Agreement has caused BMS to lose at least a year's worth of sales of branded Reyataz[®] to Venezuela. At this juncture, BMS estimates that its losses exceed \$15 million.

PARTIES

9. BMS is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in New York.

10. Upon information and belief, Mylan is a corporation organized and existing under the laws of India with its principal place of business in India. Upon information and belief, Mylan is in the business of, among other things, manufacturing, marketing and selling generic pharmaceutical products throughout the United States, including within this judicial district. Upon information and belief, Mylan is one of the world's largest generic drug manufacturers.

JURISDICTION AND VENUE

11. This is a civil action seeking damages under New York contract law.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a) because: (i) there is diversity of citizenship between Plaintiff and Defendant; and (ii) the matter in controversy exceeds \$75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Mylan because, on information and belief, Mylan does business in New York and has purposefully availed itself of the benefits and protections of the laws of New York such that it should reasonably anticipate being haled into court here. Defendant also has continuous and systematic contacts with this judicial district,

including on information and belief, selling and shipping pharmaceutical products in New York, causing others to use, offer to sell, or sell pharmaceutical products in New York, and deriving substantial revenues from those sales. Upon information and belief, Mylan has previously consented to jurisdiction in this Court.

14. Venue is proper in this District under 28 U.S.C. § 1391(c)(3) because Defendant is not a resident of the United States.

RELEVANT TERMS OF THE AGREEMENT

15. The Agreement begins with general recitals:

WHEREAS, BMS is the owner or licensee of certain know-how relating to the manufacture of such compounds and/or compositions; and

WHEREAS, Company [Mylan] wishes to import the compounds into the Territory, or manufacture such compounds in the Territory, for formulation into pharmaceutical compositions in the Territory, and to sell or to otherwise distribute the pharmaceutical compositions for the treatment of HIV/AIDS in the Territory; and

WHEREAS, in furtherance of BMS' commitment to extending the survival and enhancing the lives of people with HIV/AIDS, by making available certain products containing the compounds in the countries of the Territory at no profit, BMS is prepared to grant immunity from suit for infringement with respect to the manufacture, use and sale in the Territory for antiretroviral drug products comprising the compounds as active ingredients under the Intellectual Property (hereinafter defined) and BMS expects that Company shall use its reasonable best efforts to make such antiretroviral drug products available in the Territory.

16. The "PURPOSE" of the Agreement is then set forth in paragraph 2.1:

The purpose of this Agreement shall be to permit Company [Mylan] to increase access to the Products for the benefit of the people in the Territory specifically for the treatment of HIV/AIDS by enabling Company to make available Products throughout the Territory with immunity from suit on any ground of Intellectual Property infringement on the terms set forth in this Agreement.

* * * *

BMS further expressly states that this Agreement shall not extend or grant immunity from suit or any other rights or privileges to Company or Company Affiliates for any sale or

distribution of Products outside the Territory nor shall any provision of this Agreement be interpreted to create a presumption or basis for any grant of right or license or future negotiation thereof. (Emphasis added.)

17. Next, the Agreement sets forth the “GRANT” of rights from BMS to Mylan:

3.1 For the avoidance of doubt, the immunity from suit, as referred to herein, shall provide to Company a defense against a suit or other enforcement of the Intellectual Property on any ground of infringement arising from Company’s exercise of the grant in accordance with the terms and conditions of this Agreement.

a. Subject to the terms and conditions set forth herein, BMS grants to Company immunity from suit under the Intellectual Property for the: (i) manufacture of Products by Company or Company Affiliates in the Territory; (ii) sale or other distribution of Products by Company or Company Affiliates, or their authorized distributors and agents, within the Territory; and (iii) use of Products obtained from Company or Company Affiliates, or their authorized distributors and agents, for treating HIV/AIDS in the Territory.

b. The immunity from suit provided by this Agreement shall not prevent the exportation of Products to or distribution of Products within countries outside the Territory where Patents do not exist. **However, the immunity from suit shall not extend to patents and patent applications not explicitly included within the Patents, nor shall it extend to know-how not explicitly included within the Know-How rights, nor shall it extend to Patents outside the Territory. (Emphasis added.)**

* * * *

d. Company and Company Affiliates shall not sell, distribute or otherwise transfer Products manufactured hereunder to any third parties it reasonably believes may export the Products outside the Territory where Patents exist.

18. Finally, as relevant to the claims here, the Agreement defines “Patent” or “Patents” to “mean the patents and patent applications described in Appendix A [which include atazanavir], and all patents issuing from such patent applications as well as all divisionals and extensions thereof.” The covered “Territory” or “Territories” are defined in Appendix C to the Agreement and are limited to the countries mostly in sub-Saharan Africa and India. The Agreement does not include Venezuela as part of the Territory.

THE CLAIM

19. On April 17, 2011, BMS and Mylan entered into the Agreement, a legally valid and enforceable contract.

20. In or about November, 2011, Mylan requested BMS's consent to distribute and sell generic atazanavir in Venezuela, a country not included in the Territories defined in the Agreement.

21. Shortly thereafter, BMS denied Mylan's request as BMS had and has patent applications pending for Reyataz[®] in Venezuela, and had sold Reyataz[®] to the government of Venezuela for at least five years. BMS also anticipated that it would soon begin negotiations with the Venezuelan government to provide Reyataz[®] in 2012, just as it had in 2011 and years prior.

22. Nonetheless, upon information and belief, in or about February, 2012, in direct conflict with BMS's decision not to permit Mylan to sell generic atazanavir to the Venezuelan market, and in breach of the Agreement, Mylan sold at least a year's worth of generic atazanavir to PAHO for the express purpose of distributing the product into Venezuela. Upon information and belief, pursuant to its agreement with PAHO, Mylan shipped atazanavir to the Venezuelan Ministry of Health² and the product is currently being sold in the Venezuelan marketplace.

23. As a result, BMS has incurred lost profits on sales to Venezuela for at least a year, which BMS estimates exceed \$15 million. Additionally, BMS's negotiation strength with the Venezuelan government going forward has been severely damaged.

² On or about March 2012, Mylan conceded that its sale of atazanavir to PAHO for this purpose breached the Agreement. As a result, Mylan committed to obtain the return of the product and to prevent its sale in Venezuela.

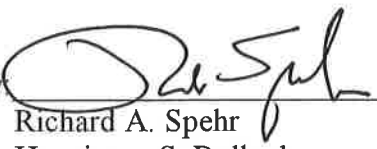
PRAYER FOR RELIEF

24. WHEREFORE, BMS demands judgment in its favor against Mylan:

- (a) awarding BMS money damages in an amount to be determined at trial, but not less than \$15 million USD plus all applicable interest;
- (b) awarding BMS the costs and disbursements of this proceeding, including reasonable attorney's fees; and,
- (c) granting such other and further relief to BMS as this Court deems just, proper, and equitable.

Dated: New York, New York
July 30, 2012

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